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T-741 P 01 F-651

FAX TRANSMISSION

DATE: August 29, 2003

PTO IDENTIFIER: Application Number 09/170,042-Conf. #6370
Patent Number

Inventor: Hastings et al.

MESSAGE TO: Examiner R.C. Hayes

FAX NUMBER: (703) 872-9307

FROM: HUMAN GENOME SCIENCES, INC.

Doyle A. Siever

PHONE: (240) 314-4400 Ext. 3595

Attorney Dkt. #: PF226D1

PAGES (Including Cover Sheet): 12**CONTENTS:**

1. Fax Cover Sheet (1 page);
2. Certificate of Transmission under 37 CFR 1.8 (1 page);
3. Fee Transmittal with appropriate fee(s) (1 page);
4. Petition for Extension of Time (2 months, to and including September 2, 2003) (1 page); and
5. Second Amendment and Reply Under 37 C.F.R. 1.116 (8 pages)

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HUMAN GENOME SCIENCES, INC.
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FAX TRANSMISSION

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**FEE TRANSMITTAL
for FY 2003**

Effective 01/01/2003, Patent fees are subject to annual revision.

☐ Applicant claims small entity status. See 37 CFR 1.27**TOTAL AMOUNT OF PAYMENT (\$)** 410.00**Complete if Known**

Application Number	09/170,042-Conf. #6370
Filing Date	October 13, 1998
First Named Inventor	Gregg A. Hastings
Examiner Name	R.C. Hayes
Art Unit	1647
Attorney Docket No.	PF226D1

METHOD OF PAYMENT (check all that apply)☐ Check ☐ Credit Card ☐ Money Order ☐ Other ☐ None☒ Deposit Account

Deposit Account Number 08-3425

Deposit Account Name Human Genome Sciences, Inc.

The Director is hereby authorized to: (check all that apply)

☒ Charge fee(s) indicated below ☒ Credit any overpayments☒ Charge any additional fee(s) during the pendency of this application☐ Charge fee(s) indicated below, except for the filing fee to the above-identified deposit account.**FEE CALCULATION (continued)****3. ADDITIONAL FEES**

Large Entity		Small Entity		Fee Description	Fee Paid
Fee Code	Fee (\$)	Fee Code	Fee (\$)		
1051	130	2051	65	Surcharge - late filing fee or oath	
1052	50	2052	25	Surcharge - late provisional filing fee or cover sheet.	
1053	130	1053	130	Non-English specification	
1812	2,520	1812	2,520	For filing a request for <i>ex parte</i> reexamination	
1804	920*	1804	920*	Requesting publication of SIR prior to Examiner action	
1805	1,840*	1805	1,840*	Requesting publication of SIR after Examiner action	
1251	110	2251	55	Extension for reply within first month	
1252	410	2252	205	Extension for reply within second month	410.00
1253	930	2253	465	Extension for reply within third month	
1254	1,450	2254	725	Extension for reply within fourth month	
1255	1,970	2255	985	Extension for reply within fifth month	
1401	320	2401	160	Notice of Appeal	
1402	320	2402	160	Filing a brief in support of an appeal	
1403	280	2403	140	Request for oral hearing	
1451	1,510	1451	1,510	Petition to institute a public use proceeding	
1452	110	2452	55	Petition to revive - unavoidable	
1453	1,300	2453	650	Petition to revive - unintentional	
1501	1,300	2501	650	Utility issue fee (or reissue)	
1502	470	2502	235	Design issue fee	
1503	630	2503	315	Plant issue fee	
1460	130	1460	130	Petitions to the Commissioner	
1807	50	1807	50	Processing fee under 37 CFR 1.17(q)	
1806	180	1806	180	Submission of Information Disclosure Stmt	
8021	40	8021	40	Recording each patent assignment per property (times number of properties)	
1809	750	2809	375	Filing a submission after final rejection (37 CFR 1.129(a))	
1810	750	2810	375	For each additional invention to be examined (37CFR 1.129(b))	
1801	750	2801	375	Request for Continued Examination (RCE)	
1802	900	1802	900	Request for expedited examination of a design application	

Other fee (specify)

*Reduced by Basic Filing Fee Paid

SUBTOTAL (3) (\$) 410.00**FEE CALCULATION****1. BASIC FILING FEE**

Large Entity		Small Entity		Fee Description	Fee Paid
Fee Code	Fee (\$)	Fee Code	Fee (\$)		
1001	750	2001	375	Utility filing fee	
1002	330	2002	165	Design filing fee	
1003	520	2003	260	Plant filing fee	
1004	750	2004	375	Reissue filing fee	
1005	160	2005	80	Provisional filing fee	

SUBTOTAL (1) (\$) 0.00**2. EXTRA CLAIM FEES FOR UTILITY AND REISSUE**

Total Claims		Extra Claims		Fee from below		Fee Paid
Total Claims	14	-41** =	0	x		
Independent Claims	2	-4** =	0	x		
Multiple Dependent						

Large Entity		Small Entity		Fee Description
Fee Code	Fee (\$)	Fee Code	Fee (\$)	
1202	18	2202	9	Claims in excess of 20
1201	84	2201	42	Independent claims in excess of 3
1203	280	2203	140	Multiple dependent claim, if not paid
1204	84	2204	42	** Reissue independent claims over original patent
1205	18	2205	9	** Reissue claims in excess of 20 and over original patent

SUBTOTAL (2) (\$) 0.00

** or number previously paid, if greater; For Reissues, see above

SUBMITTED BY

Name (Print/Type) Doyle A. Siever

Registration No. (Attorney/Agent)

47,088

Complete (if applicable)

Telephone (240) 314-4400

Signature

Date

August 29, 2003

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1. Fax Cover Sheet (1 page);
2. Certificate of Transmission under 37 CFR 1.8 (1 page);
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September 2, 2003) (1 page); and
5. Second Amendment and Reply Under 37 C.F.R. 1.116 (8 pages).

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Hastings et al.

Docket No.: PF226D1

Application No.: 09/170,042

Group Art Unit: 1647

Filed: October 13, 1998

Examiner: R.C. Hayes

For: Human Neuronal Attachment Factor-1

PETITION FOR EXTENSION OF TIME UNDER 37 C.F.R. § 1.136(a)

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450


Sir:

Applicants hereby petition for an extension of time to and including September 2, 2003 (September 1st being a Federal Holiday, *i.e.*, Labor Day) to respond to the Advisory Action mailed August 1, 2003.

The Commissioner is also authorized to charge any additional required fee or credit any overpayment in connection with this submission to our Deposit Account. In the event that a further petition for an extension of time is required to be submitted at this time, Applicants hereby petition for an extension of time for as many months as are required to ensure that the above-identified application does not become abandoned.

Dated: August 29, 2003

Respectfully submitted,

By 

Doyle A. Siever

Registration No.: 47,088
HUMAN GENOME SCIENCES, INC.
9410 Key West Avenue
Rockville, Maryland 20850
(240) 314-4400

KKH/MJH/DA/ba

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REPLY UNDER 37 C.F.R. § 1.116 – EXPEDITED PROCEDURE
EXAMINING GROUP 1647

VIA FACSIMILE AUGUST 29, 2003

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Hastings, et al.

Docket No.: PF226D1

Application No.: 09/170,042

Group Art Unit: 1647

Filed: October 13, 1998

Examiner: R.C. Hayes

For: Human Neuronal Attachment Factor-1

SECOND AMENDMENT AND REPLY UNDER 37 C.F.R. §1.116

Mail Stop AF

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In response to the Advisory Action mailed August 1, 2003 (Paper No. 18), please enter the following amendments and consider the following remarks. Applicants submit concurrently herewith: (a) a Fee Transmittal Sheet; (b) Petition for an Extension of Time (two months to and including September 2, 2003 (September 1st being a Federal Holiday, *i.e.*, Labor Day); and (c) a Certificate of Transmission Under 37 C.F.R. § 1.8.

Amendments to the specification begin on page 2.

Amendments to the claims begin on page 3.

Remarks begin on page 6.

COPY

Amendments to the Specification:

On page 12, please replace the third paragraph at lines 22-35 with the following amended paragraph:

The present invention further relates to polynucleotides which hybridize to the hereinabove-described sequences if there is at least 70%, preferably at least 90%, and more preferably at least 95%, 96%, 97%, 98% or 99% identity between the sequences. The present invention particularly relates to polynucleotides which hybridize under stringent conditions to the hereinabove-described polynucleotides. As herein used, the term "stringent hybridization conditions" is intended overnight incubation at 42° C in a solution comprising: 50% formamide, 5x SSC (~~750 mM~~ ~~150 mM~~ NaCl, 75 mM ~~15 mM~~ trisodium citrate), 50 mM sodium phosphate (pH 7.6), 5x Denhardt's solution, 10% dextran sulfate, and 20 µg/ml denatured, sheared salmon sperm DNA, followed by washing the filters in 0.1x SSC at about 65° C. The polynucleotides which hybridize to the hereinabove described polynucleotides in a preferred embodiment encode polypeptides which either retain substantially the same biological function or activity as the mature polypeptide encoded by the cDNAs of Figure 1 (SEQ ID NO:1).

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Amendments to the Claims

This listing of claims will replace all prior versions and listings of claims.

1 – 27. Cancelled.

28. (Previously Presented) An isolated polypeptide comprising an amino acid sequence selected from the group consisting of:

- (a) amino acids 1 to 331 of SEQ ID NO:2;
- (b) the complete amino acid sequence encoded by the cDNA clone contained in ATCC Deposit No. 97343;
- (c) amino acids 2 to 331 of SEQ ID NO:2;
- (d) the complete amino acid sequence excepting the N-terminal methionine encoded by the cDNA clone contained in ATCC Deposit No. 97343;
- (e) amino acids 24 to 331 of SEQ ID NO:2;
- (f) amino acids 27 to 331 of SEQ ID NO:2; and
- (g) the amino acid sequence of the mature form of NAF-1 encoded by the cDNA clone contained in ATCC Deposit No. 97343.

29. (Previously Presented) The isolated polypeptide of claim 28 wherein said amino acid sequence is (a).

30. (Previously Presented) The isolated polypeptide of claim 28 wherein said amino acid sequence is (b).

31. (Previously Presented) The isolated polypeptide of claim 28 wherein said amino acid sequence is (c).

32. (Previously Presented) The isolated polypeptide of claim 28 wherein said amino acid sequence is (d).

COPY

33. (Previously Presented) The isolated polypeptide of claim 28 wherein said amino acid sequence is (e).

34. (Previously Presented) The isolated polypeptide of claim 28 wherein said amino acid sequence is (f).

35. (Previously Presented) The isolated polypeptide of claim 28 wherein said amino acid sequence is (g).

36 – 67. (Cancelled).

68. (New) An epitope bearing fragment of the human NAF-1 polypeptide selected from the group consisting of:

(a) an epitope bearing fragment consisting of at least amino acids 75 to 100 of SEQ ID NO:2;

(b) an epitope bearing fragment consisting of at least amino acids 168 to 180 of SEQ ID NO:2;

(c) an epitope bearing fragment consisting of at least amino acids 204 to 226 of SEQ ID NO:2;

(d) an epitope bearing fragment consisting of at least amino acids 258 to 281 of SEQ ID NO:2; and,

(e) an epitope bearing fragment consisting of at least amino acids 291 to 327 of SEQ ID NO:2.

69. (New) The epitope bearing fragment of claim 68 wherein said fragment is (a).

70. (New) The epitope bearing fragment of claim 68 wherein said fragment is (b).

71. (New) The epitope bearing fragment of claim 68 wherein said fragment is (c).

COPY

72. (New) The epitope bearing fragment of claim 68 wherein said fragment is
(d).

73. (New) The epitope bearing fragment of claim 68 wherein said fragment is
(e).

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Remarks

The Examiner has issued an Advisory Action and did not enter Applicant's first After Final amendment submitted on July 1, 2003. *See*, Paper No. 18. Therefore, Applicants submit herein a Second Amendment cancelling all previously rejected or canceled claims (*i.e.*, claims 1-27, 36-37, and 43-61). Applicants acknowledge and thank the Examiner for allowance of claims 28-35. *See*, Paper No. 18. Applicants have also cancelled claims 38-42 (and the corresponding unentered claims 62-67) and re-presented these in independent form (new claims 68-73) as suggested by the Examiner. *See*, Paper No. 16, page 2, item 6. Accordingly, the subject matter of claims 38-42 has been incorporated into independent Markush-type claim 68. Upon entry of the present amendment, claims 28-35 and 68-73 will be pending. No new matter has been added.

I. Amendments to the Specification

Applicants have also discovered an obvious typographical error in the specification. Accordingly, the specification has been amended with respect to correction of the NaCl and trisodium citrate concentrations for 5xSSC disclosed on page 12, lines 28-29 of the specification. An amendment to correct an obvious error does not constitute new matter where one skilled in the art would not only recognize the existence of the error in the specification, but also the appropriate correction. *See*, M.P.E.P. § 2163.07. Here, the recognition of the typographical errors, along with the correction of the errors in the specification and claims and in the ingredient amounts listed for 5x SSC is obvious to one skilled in the art; therefore, the correction does not constitute new matter.

In particular, 5x SSC is a component of many hybridization solutions and is well known in the art. (*See*, e.g., Exhibit A, CURRENT PROTOCOLS IN MOLECULAR BIOLOGY, John Wiley and Sons, N.Y., at page 2.10.7 (1989)). SSC is normally made as a 20x stock solution, and then diluted accordingly for a particular use. Exhibit A also shows that a 20x SSC stock solution contains 3 M NaCl and 0.3 M trisodium citrate. (*See*, e.g., Exhibit A, CURRENT PROTOCOLS, at page A.2.5.) To make a 5x SSC solution, the 20x solution must be diluted by a factor of four. Therefore, a 5x SSC solution contains 750 mM NaCl ($3\text{ M} \div 4 = 750\text{ mM}$) and 75 mM trisodium citrate ($0.3\text{ M} \div 4 = 75\text{ mM}$). One skilled in the art would have immediately recognized that the amounts of ingredients

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listed in the specification for a 5x SSC solution was incorrect. Rather than describing a 5x SSC solution, made up of 750 mM NaCl and 75 mM trisodium citrate, the specification inaccurately listed the ingredient amounts for a 1x solution. The skilled artisan, in recognizing the typographical error, could have easily adjusted the amount of ingredients described in the specification to properly make a 5x SSC solution.

Therefore, because no new matter will be added to the specification if these typographical errors are corrected, Applicants respectfully request that the amendments to the specification to recite the correct concentrations of sodium chloride and sodium citrate in 5x SSC be entered.

II. Claims 38-42

Claims 38-42 were objected to as being dependent upon a rejected base claim, "but would be allowable if rewritten in independent form..." *See*, Paper No. 16, page 2, item 6.

To comply with the Examiner's instruction, Applicants have herein cancelled claims 38-42 and rewritten the subject matter encompassed therein in independent claim 68 and dependent claims 69-73. Accordingly, the independent Markush-type claim 68 encompasses the subject matter of previously pending claims 38-42; dependent claim 69 corresponds to previously pending claim 38; claim 70 corresponds to 39; claim 71 corresponds to 40; claim 72 corresponds to 41; and, claim 73 corresponds to 42. No new matter has been added by the amendments made herein. Accordingly, Applicants respectfully request entry of the above amendments and allowance of claims 68-73.

Conclusion

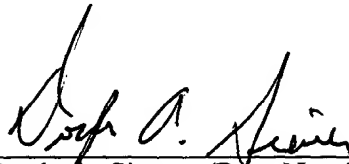
Applicants believe that this application is in condition for allowance. The Examiner is invited to call the undersigned at the phone number provided below if any further action by Applicants would expedite the allowance of this application.

Applicants believe that there are no fees due in connection with the filing of this paper. However, should a fee be due, please charge the fees to our Deposit Account No. 08-

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3425. If a fee is required for an extension of time under 37 C.F.R. § 1.136, such an extension is requested and the appropriate fee should also be charged to our Deposit Account.

Respectfully submitted,



Dated: August 29, 2003

Doyle A. Siever (Reg. No. 47,088)
Agent for Applicants

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9410 Key West Avenue
Rockville, MD 20850
Telephone: (240) 314-4400 ext.3595

KKH/MJH/DAS